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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------------------------|-------------|----------------------|---------------------|------------------|
| 10/697,463 | 10/30/2003 | Kevin S. Marchitto | D6323D | 7989 |
| 7590 | | 11/14/2007 | EXAMINER | |
| Benjamin Aaron Adler, Ph.D., J.D. | | | HANLEY, SUSAN MARIE | |
| Adler & Associates | | | ART UNIT | PAPER NUMBER |
| 8011 Candle Lane | | | 1651 | |
| Houston, TX 77071 | | | | |

| | |
|------------|---------------|
| MAIL DATE | DELIVERY MODE |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | |
|------------------------------|------------------------|---------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 10/697,463 | MARCHITTO ET AL. |
| | Examiner | Art Unit |
| | Susan Hanley | 1651 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 14 June 2007.
 2a) This action is **FINAL**. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1 and 5-11 is/are pending in the application.
 4a) Of the above claim(s) 7 and 8 is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 1, 5 and 9-11 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

The remarks and amendment filed 6/14/07 are acknowledged.

Claims 1 and 5-11 are pending.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Election/Restrictions

Applicant's election without traverse of the specie comprising molecules that reach a transition state in a biochemical reaction in an enzyme linked immunoassay with electromagnetic energy in the range of 200-20,000 nm in the reply filed on 4/21/06 is again acknowledged.

Claims 7 and 8 stand withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made without traverse in the reply filed on 4/21/06.

Claim 1, 5, 6 and 9-11 remain under examination.

Terminal Disclaimer

The terminal disclaimer filed on 6/14/07 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of Application No. 10/774,320 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Response to Arguments

Applicant's arguments regarding the prior art rejection in the last Office action have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 5, 6 and 9-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 10108663 (1998; machine translation) in view of Northrup et al. (WO 96/41864).

JP 10108663 discloses a method for increasing the rate of enzyme-catalyzed reactions such as ELISA, gene amplification, and restriction enzymes, as well as the cultivation of plant tissue, microbes and yeast with a micro-incubator that heats the reaction chamber up to 37 degrees C. (p. 2 of the machine translation). The micro-incubator comprises a motor for stirring, a heater and fan

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(p. 8). An ELISA procedure was carried out in the micro-incubator at 25 and 37 degrees C. The efficiency of the ELISA reaction was increased by a factor of 1.5 at the higher temperature (p. 7). This disclosure meets, in part, the limitations of claims 1 and 9 because the reactants and medium needed for an ELISA are placed in a chamber to which energy (heat) is applied. The rate of the ELISA reaction was increased by a factor or 1.5 at the higher temperature (e.g., the molecular state, as in instant claim 9). The disclosure of the JP 10108663 meets, in part, the limitations of claims 1, 10 and 11 because the document reports that the claimed physical limitations (putting the ELISA reactants in a vessel and transducing energy (heat) into the vessel) were carried out to produce the claimed outcome (increasing the product formation of the ELISA reaction). The mechanism of altering the molecular state of one or more of the reactants (e.g., reactant configuration and the transition state thereof) is a feature that flows from the process. The mechanism of the process of the alteration of the molecular state does not bear on the patentability of the claimed process because further characterization of what occurs in a known method does not impart patentability because the outcome of the method is the same. See *Ex parte Novitski*, 26 USPQ 2nd 1389 (BOPA 19j3).

JP 10108663 does not disclose that the micro-vessel heating device used to accelerate the efficiency of the EISA reaction employs electromagnetic energy that is radiant energy with a wavelength from 200 nm to about 20,000 nm.

Northrup discloses a diode laser heated micro-reaction chamber for inorganic, organic and biochemical reactions. Northrup exemplifies PCR. The heat source is optical and the heat therefrom directly includes reactions. The light is emitted from a laser and can be IR, UV or visible (p. 4 and p. 6). The optically-heated microchamber is advantageous because it is very precise and also has a

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detector that can sense microliter to picoliter samples (p. 5). sources are used to generate heat for the PCR thermal cycle (abstract). Northrup teaches the selection of wavelengths for the desired heat (p. 9).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ the optically-heated micro-reaction chamber of Northrup to carry out the heat-enhanced ELISA reaction disclosed by JP 10108663. The ordinary artisan would have been motivated to do so because the optically-heated microchamber of Northrup provides a heated chamber for enzyme reactions as well as a detector to monitor product formation. Northrup specifically recommends enzymatic reactions and PCR as suitable for the optically heated microchamber. JP 10108663 disclosed a conventionally heated microchamber for ELISA and PCR-type reactions. Thus, the ordinary artisan would have realized that the optically-heated microchamber of Northrup serves the same purpose as the microchamber taught by JP 10108663 and the optically-heated microchamber is more precise and has a product detector. The ordinary artisan would have had a reasonable expectation that rate-enhanced ELISA reactions could be carried out in the optically-heated microchamber of Northrup because Northrup teaches how to transduce an appropriate amount of heat to the chamber based on the wavelength of the electromagnetic radiation.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Hanley whose telephone number is 571-272-2508. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Susan Hanley
Patent Examiner
AU 1651



SANDRA E. SAUCIER
PRIMARY EXAMINER